4 December 2013

EU-US Transatlantic Trade and Investment Partnership - ECHA input on CoRAP, SVHC Roadmap and processes for risk management under REACH and CLP

1. Introduction

The second round of the TTIP negotiations took place 11-15 November 2013. At the meeting, it was agreed that both sides would prepare ahead of the next round (16 to 20 December) some further documents to work out details for a possible co-operation on 'prioritisation of chemicals for assessment and assessment methodologies'.

This paper summarises the ECHA input on the following:

- A description of the process for **CoRAP** updates: who does what, and when?
- A description of the **SVHC Roadmap** implementation plan and Communication strategy
- A description of the **restrictions/authorisation/harmonised C&L** processes

2. CoRAP Process Description

Under REACH substance evaluation process Member States evaluate certain (priority) substances to clarify whether their use poses a risk to human health or the environment. The objective is to decide whether it is necessary to request further information from the registrants of the substance to verify the suspected concern.

The evaluation may in the end conclude that the risks are sufficiently under control with the measures already in place. Otherwise, it may lead to the proposal of EU-wide risk management measures such as restrictions, identification of substances of very high concern, harmonised classification or other actions outside the scope of REACH.

In cooperation with the Member States, ECHA defines risk-based criteria and then selects the substances that are to be evaluated. The selected substances are listed by ECHA in the Community Rolling Action plan (CoRAP) following the opinion of the Member State Committee. An evaluating Member State will be designated for each substance on the final CoRAP. The plan will always comprise of three consecutive years and the plan is annually updated. Usually in each March a new CoRAP with plan of 3 years is adopted and published. For each substance listed from 2013

onwards a justification document giving the reasons for inclusion in CoRAP is also published.

The initial reason for selecting a substance for the CoRAP is not limiting the scope of the evaluation. During the evaluation, the Member State may identify other concerns that need clarification in order to conclude whether a substance is of concern or not. However, the Member State may focus the evaluation more upon certain aspects of the substance.

The substance evaluation process assesses all registration dossiers from all registrants specific to the same substance, i.e. in order to take into account the combined exposure. Other available sources of information are also considered.

The evaluating Member State has 12 months from the publication of the CoRAP to decide whether it needs to request further information from the registrants to clarify the concern. This request might go beyond the standard information requirements of REACH (Annexes VII to X) and may pertain to the intrinsic properties of the substance or its exposure. For example, registrants may need to provide studies on mode of action or monitoring of concentration levels in organisms or the environment.

The view that further information is needed is shared with all the other Member States and ECHA to achieve a general agreement. ECHA takes the decision to request for further information should this be necessary.

All decisions taken, finalised conclusions documents and substance evaluation reports will be published on ECHA website.

Further information can be found on ECHA's website at:

http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation

and http://echa.europa.eu/documents/10162/13628/sub_eval_under_reach_leaflet_en.pdf

The procedure describing the process of establishing updates of the Community Rolling Action Plan (CoRAP):

http://echa.europa.eu/documents/10162/13607/pro_0022_01_substance_eva_establishing_updates_of_corap_en.pdf

http://echa.europa.eu/documents/10162/13578/wp_msc_community_act_plan_en.pdf

The Community Rolling Action Plan (CoRAP):

http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

3. SVHC Roadmap

The European Union has set an important goal for Europe to have all relevant substances of very high concern (SVHCs) included in the Candidate List by 2020. This ambitious EU commitment has now been translated into practical steps in the SVHC Roadmap to 2020. ECHA has been working with the European Commission and the Member State competent authorities to develop an implementation, which

outlines a methodology for working towards achieving the objectives, with clear deliverables, planning and sharing of responsibilities.

One of the elements planned under the implementation of the SVHC Roadmap is increased transparency, to help stakeholders to understand the roadmap's objectives and scope. Increased transparency will also increase the predictability for companies on how substances will be managed by the regulatory authorities.

With this aim in mind, ECHA launches in mid-December a new section of the website to give stakeholders and the public the opportunity to access easily relevant roadmap information.

SVHC Roadmap information:

http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern

4. Risk management under REACH and CLP

4.1 Authorisation

The authorisation procedure aims to assure that the risks from Substances of Very High Concern are properly controlled and that these substances are progressively replaced by suitable alternatives while ensuring the good functioning of the EU internal market.

Substances with the certain hazard properties may be identified as Substances of Very High Concern (SVHCs).

The authorisation process involves three steps: i) identification of SVHCs; ii) recommendation for inclusion in the Authorisation List; and iii) applications for authorisation. ECHA consults the public during all three steps and encourages all interested parties to get involved and give their views.

	Identification of SVHCs (more)	**Recommendation for inclusion in the Authorisation List (more)**	**Applications for authorisation (more)**
Purpose	To identify which substances will be included in the Candidate List	To gather information to assist decision making on when Candidate List substances will be subject to the authorisation requirement	Whether the use of the substance (as applied for by the applicant) can continue after the sunset date
What is prepared and by whom?	Annex XV report prepared by Member States or ECHA (on behalf of COM)	Draft recommendation prepared by ECHA	Relevant parts of the applications for authorisation prepared by industry

Factors considered during each step of the process	Intrinsic properties of the substance	All uses of the substance within the scope of the authorisation requirement	Use(s) applied for by an applicant: Control of risks Availability of suitable alternatives Socio-economic consequences of continued use
Type of information requested	Identity of the substance and intrinsic properties relevant for the identification (unless identification is based on harmonised classification and labelling and cannot be challenged in this context). Additionally, information on uses, exposures and alternatives	Uses and volumes used. Complexity of the supply chain; views on the transitional arrangements and possible exemptions	Alternative substances or technologies to the use(s) applied for; risks, technical feasibility and costs of alternatives
When will it take place?	Twice a year (45 days in March-April and September-October)	Once a year (90 days in June-September)	Quarterly (eight weeks in February, May, August and November)

Basic information of the process:

http://www.echa.europa.eu/web/guest/regulations/reach/authorisation

The process description for applications for authorisation (with a graph):

http://echa.europa.eu/regulations/reach/authorisation/applications-for-authorisation

ECHA has also published a revised factsheet on application for authorisation, which could be of interest:

http://echa.europa.eu/documents/10162/13637/factsheet_applications_authorisation_en.pdf

A presentation on the EU risk management that provides an overview of the authorisation process is attached in a separate document.

4.2 Restrictions

Restrictions are a tool to protect human health and the environment from unacceptable risks posed by chemicals. Restrictions may limit or ban the manufacture, placing on the market or use of a substance.

A restriction applies to any substance on its own, in a mixture or in an article, including those that do not require registration. It can also apply to imports.

Basic information of the process is available at:

http://www.echa.europa.eu/web/guest/regulations/reach/restriction

The restriction process description (with a graph) is here:

http://www.echa.europa.eu/web/guest/regulations/reach/restrictions/restriction-procedure/restrictions-process

A presentation on the EU risk management that provides an overview of the restriction process is attached in a separate document.

4.3 Harmonised Classification and Labelling

Certain situations require that the classification of a substance is harmonised and made obligatory at Community level to ensure an adequate risk management throughout the European Community.

This could happen in three situations:

- Where the substance is either carcinogenic, mutagenic, toxic for reproduction or a respiratory sensitizer.
- When the substance is an active substance in biocidal or plant protection products.
- When it is justified that a classification at EU level is needed.

Member States, manufacturers, importers and downstream users may propose the classification and labelling of a substance to be harmonised across the European Union.

The intention to prepare a harmonised classification and labelling proposal is made public on the registry of intentions to allow interested parties to prepare their contribution to the process.

Basic information of the process is available at:

http://echa.europa.eu/web/guest/regulations/clp/harmonised-classification-and-labelling

and

http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/harmonised-classification-and-labelling

The procedure describing the harmonisation of classification and labelling process as stated in the CLP Regulation:

http://echa.europa.eu/documents/10162/13607/procedure_harmonisation_classification_labelling_en.pdf

A presentation giving an overview of ECHA's C&L tasks is attached in a separate document.